July 19, 2003

Comments sent to the EPA on human testing of pesticides.

I am adamant that pesticides should not be tested on innocent people for both ethical and scientific reasons.

I am Canadian but I feel that I have to comment on this issue as the PMRA closely works with the US EPA.

First, here is my personal experience.

I have suffered accidental pesticide poisoning several times. The first time I was aware of it, my dad had asked me to use one of these canes to get rid of dandelions. I was 13 (1967). Of course I wore no protective clothing but I did scrub my hands really well before supper. It did not help. My parents found me on the hallway floor, where I had fallen after losing consciousness. I stayed unconscious 2 or 3 days and stayed weak for quite a while after. Before the incident, I had great vision, then it started declining fast.

I was undoubtedly exposed many more times as my dad used quite a bit around the house and I know I was sprayed over by crop sprayers in Nicaragua and traveled in a car newly sprayed at every border point across Central America. I was sick enough at that time, it was hard to know from what...

My downfall came after I moved to Saskatchewan, where we use 36 % of Canadian pesticides. In retrospect, I was poisoned severely at least twice during field work (I am a biologist) and stayed with very persistent "hay fever" and flu symptoms for weeks. I started realizing a relationship between pesticides and health a few years later when I felt tremendous pain in the one hand that had picked up a bottle of fungicide on a store shelf. The acute severe pain was followed by numbness creeping up my arm, until I realized what had happened and washed my hands thouroughly, after which the symptoms reversed. That was around 21 years ago. After that, I never touched the stuff again myself. I became chemically sensitive and was close to death several times in the early years until I learnt to appropriately deal with the illness and developed “survival” strategies.

Starting in 1987, I had several severe reactions to unknown pesticides but I was able to track one exposure to *Linuron*. These reactions varied but usually included severe neuropathy and partial paralysis, severe loss of weight, severe lung congestion relieved only by moving out of my home during the usual *2,4-D* lawn spray spring and fall madness. *Cygon 2E* sprayed in their yard by neighbours in an over 60 km/hour wind where it ended up drenching me in my yard caused severe nausea and gastro-intestinal symptoms while I was nursing my son. Thankfully, I had enough frozen breast milk that I could just throw away 3 days worth of current one…

While I am getting better at avoiding exposures by, for instance, leaving my home without any compensation during the 2,4-D madness, wearing rubber boots or shoes all summer because of how often sidewalks are sprayed with RoundUP, and carrying my gas mask with me everywhere, I still regularly get exposed and sick, but mostly not as much.

I will have you notice that all these early times I got sick, I got sick first, then put things together later. I also was your average unconscious person and did not expect any problem from pesticide use or exposure.

Here are some comments I wrote on one such human study:

The pesticide industry financed several health effects of pesticides trials on human beings. It is pressuring the US EPA to accept evidence of such trials in its pesticide licensing and reevaluation decisions, even though they may be scientifically invalid, as well as totally unethical.

For instance, Bayer's *azinphos methyl* study was **scientifically invalid** because:

* It tested only eight adult males, whereas a test of more than 2,500 people is needed to yield statistically valid results for certain effects; [but then, of course, you usually determine NOELs (No Adverse Effect Level) on no more animals than that, correct?]

* What NOEL? In my recent research on malathion, I am finding NOELs for all kinds of things: oral, inhalation, and dermal exposure, cancer, genotoxicity, birth defects, neurotoxity and, in the case on inhalation exposure to malathion, I find in your own EPA documents that there is no NOEL determined yet for severe lesions of the respiratory system as they occurred at all levels of exposure!

* Regulatory agencies still have so many holes to plug in your risk assessments such as developmental toxicology studies (only 9 of your over 140 identified pesticides have that info yet), low level and endocrine-effects studies for which there are not yet any guidelines, that what would one NOEL for one condition mean for human safety anyhow?

* Let's face it, most of us would not think of swallowing large doses of pesticides. Most of us are exposed through inhalation, at low dose, and most unwillingly and unknowingly, and so is the rest of the environment. How relevant is an high or medium dose ingestion study anyways? The inhalation toxicity of pesticides is often increased by inhalation (20 times for malathion) and yet these are the hardest NOELs to find…

* It did not yield results relevant to children or women, or unhealthy people of all ages;

*It did not account for "in-species" natural genetic variation in susceptibility which has apparently been observed to be up to 10,000 times for at least some factors, or for synergistic effects with other pesticides, drugs or pollutant, such as when a needed detoxification enzyme is already busy detoxifying something else, therefore significantly increasing the toxicity of a pesticide.

* In this particular study, I understand there **were at least 67 "adverse events," including symptoms often associated with organophosphate poisoning;** all eight dosed subjects suffered from such "events" (including chronic headaches, nausea, abdominal pain, etc.). However**, all "events" were attributed, without detailed medical explanation, to a "virus" or the "ward environment**," even though most of these events occurred in the dosed group, and two of the placebo subjects suffered no such events.

Basically, there are so many "spin" ways to invalidate such a study, from the choice of subjects to limiting what effects you look for, to interpretation of results, that I don't see that it would have any validity. I would trust it a lot more if don by truly independent scientists, instead of industry-paid ones.

Bayer conducted the study to try to establish a less protective *no adverse effects* level (NOEL)." The unscientific unwarranted conclusion to such a study is that at the level of exposure tested, there were no effects of the pesticide. The only science I see here is the one of falsification to the point of ridicule.

If ever the PMRA or the US EPA accept such studies in their pesticide evaluations, as far as I am concerned, you lose the last shred of your credibility! You won't pass the laugh test!

Other issues that will have to be dealt with are those of **exposure and drift**. The following will likely help explain why there are so many cases of pesticide poisonings even when used according to label instructions. According to the recent report *Secondhand pesticides*, by Californians for Pesticide Reform, when levels of several volatile pesticides were **appropriately measured** (with aerosol samplers) both close and further away (in some towns), the Hazard Quotient for several exceeded many times (over 100 times for chlorpyrifos) the level deemed

“acceptable’ by EPA. How good is any NOEL if there is no way of ensuring that people are not exposed to levels higher than what is deemed safe?

My recent review of Malathion air concentrations during and after ULV spraying came up with a lot of really bad science, such as measuring concentrations and drift of an aerosol with an average diameter of 15 um with filter paper or cards on which other studies showed that the smallest diameter deposited was 50 um and measured 4.4 times less colonies on cards than aerosol. The Canadian recommended spraying rates are all based on assumptions and modeling and absolutely no measurements. (I have correspondence to show that). According to their own ssumed air concentrations, the hazard quotient as measured in Secondhand pesticides would exceed the levels deemed acceptable by a minimum of 12 times…A NOAEL is the basis for all risk evaluation calculations, but what good is it when air measurements concentrations are missing or normally exceed the level determined acceptable with current and normal use?

Here is essentially what one recent ULV Bti study has shown:
Aerosol spray moves a lot, is small enough to be breathable, and staying indoors offer little protection: One Canadian study (1) measured indoor and outdoor numbers of live colonies of Btk in Victoria during the Gypsy Moth Spray Program. They measured with the usual cards (Kromecote) traditionally used to measure drift and, at the same location, with an aerosol sampler. What they found is worth thinking about. While the ULV spraying was aiming for a target droplet size of 125 um,
a. the only droplets found on the drift (Kromecote) cards were between 50 – 150 um in size

b. **the droplet size was a lot smaller than planned**, averaging 4.3-7.3 um in the aerosol measured, within breathable range, and able to reach the small airways of the respiratory tract.

c. **drift outside the area**: even when the Kromecote cards showed no drift, aerosol was still measured in most cases. There was no correlation between the bacterial concentration and distance, i.e. there were just as many bacteria 1000 meters away as close to the sprayed area; the Btk geometric mean Btk concentrations of adjacent zones was often twice the one of inside the spray zone during spraying.

d. on average, the Kromecote card sample concentrations were 4.4 times lower than aerosol sampling

e. **Staying indoors does not offer much protection**: the concentrations indoors started approaching the outdoor concentrations after 2-3 hours, reached 1/3 of original outdoor concentration after 5-6 hours and, at that time, exceeded outdoor concentrations. Indoor concentrations had no correlation with any of the measured characteristics of the indoor environment, or whether doors and windows were open or shut. (1)

Regulatory agencies need to redefine drift to include evaporative drift and demand proper aerosol measurements for all studies before any of your calculations are valid.

1. Kay Teschke et al; **Spatial and Temporal distribution of Airborne *Bacillus thuringensis* var *kurstaki* during an Aerial Spray Program for Gypsy Moth Eradication;** environmental Health Perspectives, vol 101/no 1/Jan 2001, p. 47-54

I just wrote a paper reviewing, among other topics, the “missing parts” of the regulatory process, mostly PMRA but also EPA. These are some exerpts:

Inherent assumptions of the regulatory system
Existing Acts and regulations a priori assume that dangerous pesticides can be managed with negligible impact on health. Health experts think, however, that given current acute and chronic pesticide-illness data, continued increase in use of many hazardous pesticides, and persistence

of these toxins in air and water, such faith appears unfounded. The rule is still that chemicals are recognized as harmful long after their use has become routine, and exposures have become widespread (mercury, lead, PCBs, alcohol, nicotine, DDT, chlorpyrifos, CCA treated wood)

These are the *disproved* assumptions under which the Canadian Regulatory System (PMRA) functions: (as well as the US legislation)
- that "the dose makes the poison", (not exclusively true e.g. endocrine and low level effects)
- that high dose studies show all the potential health effects
- that there is a threshold below which there are no effect (NOAEL)
- that there is an immediate cause and effect
- that pesticide exposures occur one pesticide at a time, with no interaction with any other substance (NOELS established on individual chemicals, right? Not even on common formulations the public may be exposed to)
- that present studies requested for registration are sensitive enough to identify functional problems
- that a new safety factor of 1000 (compared to 100 before) will account for most of human variability as well as children's special vulnerability
- acting as if all the data and studies (nervous, immune, hormonal system, developmental nervous, immune and hormonal systems) have been performed for all registered pesticides.
- that pesticide exposures are quickly over and do not accumulate in the body (except for organochlorines like DDT)
- that because something is written on a label, it means the instructions or precautions will be followed.
- it assumes that all formulants not listed by EPA are safe and do not have to be disclosed
- and, finally, that regulating pesticides will decrease risk and use.

These assumptions are still underlying C-8, the new Canadian Pest Control Products Act (PCPA 2002). They have all been disproved.

Slow response
Any regulatory system is slow to respond. When a problem is identified, it takes years to determine needed new studies (appropriate studies for regulatory purposes still have to be defined in several fields such as hormone-disrupting and low-dose studies), years more for industry to carry them and submit the results, and years more before these are evaluated. *During all this time, there is nothing in PMRA' s or EPA's information on approved pesticides indicating what needed studies have not yet been submitted or have been waved for a particular product to meet new guidelines* (e.g. no immune, hormone-disrupting or developmental neurotoxicology studies submitted). When uses are cancelled or labels have to be changed to new "safer" tolerance levels, the changes cannot become legal until companies have effected the label change, which can take from 1 to 4 years.

How can anyone say a particular product is safe when there are so many studies missing for each? Or that it is safe after a use is cancelled or a label changed, when pesticide products keep on being sold for up to several years for uses judged inappropriate, and with inappropriate labels. What does a NOEL based on 8 unrepresentative people prove anayway?

Outdated and Costly
However, even the best regulatory systems are always outdated. The more measures, the more tests, the more the cost increases. In 1971, the total U.S. expenditures on pesticide regulation and management of pesticide risk was 4.8% of sales, 11.4% in 1996, and estimated at 16% in 2020, assuming no public concern change in priorities and, so far, no reduction in risk. By comparison, assuming a national U.S. commitment to *bio-intensive* Integrated Pest Management (IPM) by 1996 would decrease these total expenditures in 2020 by 20%, with an estimated 75% reduction in overall risks. **The only full-proof way to decrease both risk and costs of pesticides is pesticide reduction.** (Pesticides at the Crossroads, Consumer Union, 1996)

Conclusion
Furthermore, present regulations have not ensured or brought about any global reduction in reliance on pesticides and pesticide use. Because pesticide use is still increasing, and the aggregate public health hazards from pesticides have not decreased since 1970 while the costs of pesticide regulation consistently increase, the only way to decrease both risks and costs is by an aggressive government policy of reduction in pesticide use, and development of alternatives to pesticides.

Many thousands of people are sickened every year from pesticide exposure, in spite of NOELs and your "on paper" risk assessment calculations and models, likely because they are so far behind the times.

Final conclusion
MY suggestion is that, to have any social justice, people who promote pesticide use and believe in them and their safety should be willing to provide their own bodies and the ones of their families, including pregnant women, to prove beyond doubt that there are no concerns with pesticide use. After all, the study would not even have to consider a placebo effect as none of them believe in it.

Even if such a study discounted all "negative events", as the azinphos methyl one did, it would still use a pure product and not the formulations the public is exposed to, and could never conclude the pesticide tested is safe. All it could say is that with that group at that level of exposure, no significant effect has been recorded.

Unfortunately, there is no social justice in this regards and all of us have been and are guinea pigs, or rats if you prefer, in a world wide, totally unregulated and unmonitored experiment. Now, industry wants to purposefully use people as guinea pigs… If you allow then to use "healthy" university students, will they stop there? How about purposefully using pregnant women to test developmental toxicity?

We all need to get off the pesticide band wagon. The EPA has done great work in its web site and information on pesticide alternatives in school. It should pursue this approach across the board and have its mandate changed to be one mainly of support of non-toxic alternatives techniques and products and safer pesticides and ban the rest, and the world will be a safer place**.**

Thank you,

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